

**REMARKS**

Claims 1-3 and 5-9 are pending. Claim 4 has been canceled.

Claims 1 and 7 have been amended to recite the subject matter of canceled claim 4.

Claims 1 and 5-7 have been amended for clarity.

No new matter has been added by way of the above-amendment.

**[I] Claim Objections**

The Examiner objects to claims 4-6 under 37 CFR 1.75(c) for improper multiple dependency. In response, Applicants have canceled claim 4 and amended claims 5 and 6 to each depend solely from claim 1. Accordingly, withdrawal of the objection is respectfully requested.

**[II] Issues Under 35 USC 112, second paragraph**

Claims 1-3 and 7-9 have been rejected under 35 USC 112, second paragraph for being indefinite. Applicants respectfully traverse the rejection.

The Examiner objects to the term "characterized by." In response, Applicants have removed this term from claims 1 and 7. As such, withdrawal of the rejection is respectfully requested.

**[III] Issues Under 35 USC 112, first paragraph**

Claims 7-9 have been rejected under 35 USC 112, first paragraph since the scope of independent claim 7 is broader than that which is enabled. Applicants respectfully traverse the rejection.

Claim 7, as originally filed, recites a polymerization step for performing a ring-opening polymerization of  $\epsilon$ -caprolactone singly *or with other compound*. The Examiner has taken the position that the present specification does not provide an enabling disclosure to teach the skilled artisan how to perform the process when  $\epsilon$ -caprolactone is used with any *other compound*.

In response, Applicants have amended claim 7 to recite that the other compound is a polymer having a hydroxyl group and/or an ester bond. The Examiner will note that there is substantial guidance provided to the skilled artisan regarding how to perform the process when  $\epsilon$ -caprolactone is used with a polymer having a hydroxyl group and/or an ester bond at page 9, line 13 *et. seq.* and each of Inventive Examples 1-5.

Accordingly, the present specification provides sufficient enablement to the skilled artisan to perform the process when  $\epsilon$ -caprolactone is used with a polymer having a hydroxyl group and/or an ester bond, as presently claimed. As such, present claims 7-9 comply with the provisions of 35 USC 112, first paragraph and withdrawal of the rejection is respectfully requested.

#### **[IV] Prior Art Based Issues**

The following rejections are pending:

(A) Claims 1-3 are rejected under 35 USC 102(b) as being anticipated by Schoen (US 3,767,627); and

(B) Claims 1-3 and 7-9 are rejected under 35 USC 102(b) as being anticipated by Suizu et al. (US 5,496,923).

Applicants respectfully traverse the rejections.

Applicants respectfully submit that claims 1 and 7, as originally filed, recite subject matter which is patentable over Schoen and Suizu *et al.* However, in order to advance

prosecution, Applicants have amended claims 1 and 7 to recite the subject matter of claim 4, a claim not currently under rejection. Accordingly, these rejections are rendered moot.

Applicants now provide the following observations regarding the teachings of Schoen and Suizu et al. with respect to certain nonlimiting embodiments of the instantly claimed invention.

[IV - (i)] Schoen:

Schoen discloses in claim 1:

“A process for the preparation of polylactones having blocked end-groups consisting essentially in reacting, in the presence of a catalyst, a starting material selected from the group consisting of a polylactone, a mixture of polylactones, or a mixture of at least one polylactone and at least one lactone monomer, with at least one modifier, said modifier containing at least one carboxylate ester group not included in a lactone ring of said starting material and said modifier further containing no reactive hydrogen substituents.”

Furthermore, Schoen defines the polylactone in claim 6 as being:

“selected from the group consisting of  $\epsilon$ -caprolactone, methyl- $\epsilon$ -caprolactone,  $\delta$ -valerolactone, methyl- $\delta$ -valerolactone, or combinations thereof.”

With respect to the reaction conditions, Schoen teaches (see column 4, lines 19-27) as follows:

“The reaction can be carried out at temperatures between about 60°C. and 300°C., but preferably at a temperature between about 100 and 200°C. To avoid degradation of the polymer and discoloration, it is preferred to carry out the modification in the absence of oxygen and water, for example, in a dry nitrogen atmosphere. The pressure at which the reaction is carried out is not critical, and may be atmospheric, super-atmospheric or below atmospheric.”

Schoen further discloses (at column 4, lines 28-34) the following:

“A procedure for performing the reaction of this invention, most simply stated, heating a polylactone melt to the required temperature, adding modifier, and adding the catalyst should this be necessary, and allowing the mixture to react for 0.5-4 hours at

elevated temperature in a dry nitrogen atmosphere, and if possible, with simultaneous agitation.”

We now turn to Suizu *et al.*

[IV - (ii)] Suizu *et al*

Suizu *et al.* disclose a purification process in claim 1 as follows:

“A purification process of an aliphatic polyester prepared in the presence of a catalyst from

- (i) an aliphatic hydroxycarboxylic acid,
- (ii) a cyclic ester of the aliphatic hydroxycarboxylic acid,
- (iii) a combination of an aliphatic polyhydric alcohol and an aliphatic polybasic acid, or
- (iv) a mixture of compounds selected from the above (i) to (iii),

which comprises deactivating the catalyst or insolubilizing and separating the catalyst, while maintaining the aliphatic polyester in a molten or a dissolved state and successively removing a low molecular weight compound by distillation under reduced pressure.”

The conditions for the purification process of Suizu *et al.* are defined in claim 2 such that the distillation is carried out "under reduced pressure ... at 120°-250°C.”

The aliphatic polyester used in the purification process of Suizu *et al.* is defined in claim 9 as being a "homopolymer of the aliphatic hydroxycarboxylic acid of the cyclic ester of the aliphatic hydroxycarboxylic acid.” In addition, the aliphatic polyester used in the purification process of Suizu *et al.* is defined in claim 10 as being a "copolymer of the aliphatic hydroxycarboxylic acid or of the cyclic ester of the aliphatic hydroxycarboxylic acid.”

With respect to preparation of aliphatic polyester and a raw material, Suizu *et al.* further disclose (at column 3, lines 47-55):

“These polymers are prepared by direct dehydration polycondensation of raw materials such as a hydroxycarboxylic acid, ... or by ring-opening polymerization of a cyclic ester intermediate of hydroxycarboxylic acid in the presence of a catalyst, for example, by suitably using a copolymerizable monomer such as lactide ... glycolide ... and  $\epsilon$ -caprolactone ...”

Suizu *et al.* disclose (at column 5, lines 1-30) the conditions for polymerization as follows:

“The ring-opening polymerization of the cyclic ester of hydroxycarboxylic acid is usually carried out without solvent and thus the polymer is in a molten state. On the other hand, the direct dehydration polycondensation is carried out in a solvent and thus the polymer is dissolved in the solvent.

The polymerized mass of the aliphatic polyester obtained by polymerization process contains several percents of unreacted raw materials, chain and cyclic oligomers and other low molecular weight compounds; an active catalyst... and a solvent depending upon the polymerization processes.

The process of the invention deactivates the catalyst... and successively removes the low molecular weight compounds. The aliphatic polyester obtained by ring-opening polymerization contains the polymer in a molten state after finishing the polymerization and thus purification is more readily carried out in view of operations by deactivating the catalyst and successively removing the low molecular compounds. On the other hand, the aliphatic polyester obtained by direct dehydration polycondensation in a solvent is preferably purified by insolubilizing and separating the catalyst and successively removing the low molecular weight compounds.

Low molecular weight compounds include oligomers having a molecular weight of 500 or less and unreacted raw materials. Particularly, cyclic esters of hydroxycarboxylic acids, for example, lactide, glycolide and  $\epsilon$ -caprolactone are preferably removed.”

Regarding purification of the aliphatic polyester, Suizu *et al.* disclose the following (at column 7, lines 6-41):

“After deactivating the catalyst or insolubilizing and removing the catalyst by these operations, the aliphatic polyester is isolated by removing the low molecular weight compounds. Removal of the low molecular weight compounds can be carried out, for

example, by dissolving the aliphatic polyester in a solvent and cooling the solution to crystallize the aliphatic polyester, by adding a lean solvent to the aliphatic polyester solution and precipitating the aliphatic polyester in the form of crystals, and by distilling off the solvent and the low molecular weight compounds from the aliphatic polyester solution. The low molecular weight compounds are preferably removed by distillation.

In the present invention, distillation of the low molecular weight compound means distillation of the low molecular weight compound dissolved in the solvent and evaporation of the low molecular weight compound contained in the polymer... The distillation is usually carried out at 300°C. or less... Thus, a preferred temperature is 250°C. or less... Thus, a preferred temperature is 120°C. or more. The pressure in the system depends upon the operation temperature and is usually 50 mmHg or less, preferably 10 mmHg or less, more preferably 5 mmHg or less.

The removal efficiency of the low molecular weight compounds contained in the aliphatic polyester can also be enhanced by ventilating an inert gas through the system in the distillation under reduced pressure... For example, the low molecular weight compounds in a homopolymer of L-lactic acid can be satisfactorily removed at 180°-200°C. for 5-6 hours under reduced pressure of 5 mmHg or less. When the distillation is carried out above 250°C., the low molecular weight compounds can be removed in an enhanced efficiency and distillation time can be reduced. However, too high a temperature is unfavorable because the polymer is liable to decompose. On the other hand, at a temperature lower than 120°C., it takes a long time to remove the low molecular weight compounds. Distillation time can be still more reduced by further reducing the distillation pressure and maintaining high vacuum.”

Regarding the objects of the invention, Suizu *et al.* disclose (at column 2, line 63 to column 3, line 17) the following:

“An object of the invention is to provide a purification process for removing cheaply and with ease in industry the low molecular weight compounds such as unreacted monomer and volatile substances which remain in the aliphatic polyester obtained by polycondensation reaction and to obtain the aliphatic polyester which has a low residual amount of the unreacted monomer and low molecular weight volatile substances and is excellent in heat resistance and weatherability.

As a result of an intensive investigation in order to solve the above problems, the present inventors have found that an aliphatic polyester which has a low content of a low molecular weight compound and is excellent in heat resistance and weatherability can be obtained by deactivating a catalyst, or by bringing an organic solvent solution of the aliphatic polyester into contact with an acid material to insolubilize and remove the catalyst in the aliphatic polyester while maintaining the aliphatic polyester in a molten or dissolved state, and successively conducting distillation or crystallization to remove the low molecular compound contained in the aliphatic polyester. Thus, the present invention has been completed.”

We now turn to the present invention.

[IV - (iii)] Comparison of Claimed Subject Matter with References:

As the MPEP directs, all the claim limitations must be taught or suggested by the prior art to establish a *prima facie* case of anticipation. See MPEP § 2131.

As is apparent from the fact that the examiner does accept the patentability of the subject matter of claim 4, both Schoen and Suizu *et al.* fail to disclose or teach the specific  $\epsilon$ -caprolactone polymer which is a copolymer of a polymer having a hydroxyl group and/or an ester bond and  $\epsilon$ -caprolactone. Since independent claims 1 and 7 have been amended to recite this feature, claims 1 and 7 are patentable over both Schoen and Suizu *et al.*

It is further noted that Schoen and Suizu *et al.* fail to disclose or teach the recovering ratio of  $\epsilon$ -caprolactone relative to caprolactone dimer in the continuous production process, although patentability does not rest on this feature.

Therefore, the claimed subject matter is novel despite the teachings of both Schoen and Suizu *et al.*

Furthermore, the present invention is non-obviousness over both Schoen and Suizu *et al.* That is, since both Schoen and Suizu *et al.* fail to disclose or teach the important elements mentioned above and the role thereof, all of the elements of the claimed subject matter would be nonobvious over the cited references.

Moreover, the present invention provides remarkable advantages which are unexpected based on the teachings of both Schoen and Suizu *et al.* That is, since both Schoen and Suizu *et al.* fail to teach the important role of the specific recovering step in combination with a specific  $\epsilon$ -caprolactone polymer (i.e., a copolymer of a polymer having a hydroxyl group and/or an ester bond and  $\epsilon$ -caprolactone), the recovering  $\epsilon$ -caprolactone from the  $\epsilon$ -caprolactone polymer would be insufficient to cause a trouble in the continuous production process.


Contrarily, according to the present invention, since  $\epsilon$ -caprolactone polymer is recovered with the specific recovering ratio relative to caprolactone dimer, the continuous production of  $\epsilon$ -caprolactone polymer can be realized without causing trouble. These advantages would not be expected over the cited references.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Garth M. Dahlen, Ph.D., Esq. (Reg. No. 43,575) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Dated: March 14, 2006

Respectfully submitted,

By  #43575  
Raymond C. Stewart  
Registration No.: 21,066 *for*  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant